EXHIBIT A

Expert Report: Thomas H. Kuehn, Ph.D.

In re Bair Hugger Products Liability Litigation

I am a mechanical engineer with extensive expertise in indoor environments, clean spaces, filtration and bioaerosols. I have been retained by 3M to provide opinions on matters pertaining to airflow and filtration concerning the Bair Hugger and its use in the operating room environment. I am being compensated at the rate of $250 per hour for my work in this case. I have not testified in any cases in the past four years.

1. Education and Experience

My complete CV is attached as exhibit A. My education includes a B.M.E. degree from the University of Minnesota in 1971 with High Distinction, and M.S. and Ph.D. degrees from the same institution with emphasis on natural convection heat transfer. I was a faculty member in the Mechanical Engineering Department at Iowa State University from 1976 to 1983. From 1983 until 2016 I was a faculty member in the Mechanical Engineering Department at the University of Minnesota. I served as the Director of the Environmental Division from 1997 to 2009 and the Director of Graduate Studies for the Mechanical Engineering and Industrial Engineering graduate programs from 1994 to 2000. At present I am a Professor Emeritus at the University of Minnesota.

I have taught many different courses in the mechanical engineering curriculum focusing on heating, ventilating and air conditioning (HVAC) topics. Course titles include "Thermodynamics", "Thermal Environmental Engineering", HVAC System Design" and "Vapor Cycle Systems". I am the lead author on one of the few text books in that area (Thermal Environmental Engineering, 3rd ed., Prentice Hall). My main professional society affiliation for the past 25 years has been the American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE). I have served on several society level committees including the Research Administration Committee, Technical Council and the Conference and Exhibition Committee. I was the lead organizer and Technical Chair for the Annual Meeting held in St. Louis, June, 2016.

My research activity has been supported by numerous state and federal agencies, companies and consortia. I have collaborated with several faculty colleagues in the Particle Technology Laboratory, the School of Public Health and the Veterinary Diagnostics Laboratory, all at the University of Minnesota. Other collaborators include faculty at other universities, researchers at federal laboratories, and research personnel at corporate laboratories.

My initial work in the area of clean rooms began in the 1980's under the sponsorship of the Particulate Contamination Control Research Consortium sponsored by several companies in the semiconductor manufacturing business. Both numerical flow simulations with airborne particle motion and experiments in semiconductor manufacturing clean rooms were performed. We published a challenge to researchers around the world in the IES Journal to submit their airflow and particle simulation results to us for comparison to measurements made in our Class 10 clean room.

The Center for Filtration Research was subsequently formed at the University of Minnesota to address issues associated with filtration of airborne particles. I have been affiliated with this Center since its founding. Much of my activity has addressed the filtration of bioaerosols including airborne bacteria, fungi and viruses. Additional support for this work has been provided by ASHRAE, NIOSH and corporations including Boeing. Capture efficiency of airborne particles versus filter type and filter loading, growth of captured particles on clean and loaded filters, and the influence of environmental parameters such as temperature, humidity and air flow rate were determined in laboratory settings, field trials or both.

Additional work on particles included a study to quantify particle removal from semiconductor wafers using megasonic cleaning. My laboratory has been very active over the past 20 years in characterizing the particle and vapor emissions from commercial cooking processes. This has resulted in new technologies being used to improve the capture of grease effluents in commercial kitchens and changes in emission regulations in the Los Angeles basin (South Coast Air Quality Management District) and the San Francisco Bay area (Bay Area Air Quality Management District).

I have worked with a group of students to design, build and operate a filter test facility that follows the requirements given in ASHRAE Standard 52.2. Our facility has extra capability for humidity control that is not included in the Standard. This facility has been used primarily to study the performance of building ventilation filters on bacteria, fungi and virus aerosols.

Students under my direction also designed, built and operated a ventilation test facility that has been used to study the movement of room air under a variety of conditions. This was designed to be operated as a one-half scale room. The supply air temperature, humidity and flow rate could be varied and the wall temperatures could be controlled separately to study the influence of combined forced and buoyancy-driven natural convection. Several air supply and exhaust configurations have been studied. Measurements in the chamber included thermocouples for temperature measurement, gas sampling probes and gas analyzers for tracer gas measurements, hot wire anemometers for velocity and turbulence measurements, and neutrally buoyant helium bubbles and water fog droplets for visualizing the air flow patterns. The chamber was also used to study the loss of infectivity of airborne virus particles as a function of room air temperature and humidity, time of flight between injection and recovery and the local UV intensity provided by UV lights installed in the upper corners of the chamber.

2. Review of Bair Hugger Filtration

I have reviewed the testimony of Karl Zgoda and Dr. Robert Crowder concerning the history of the filter media used in the Bair Hugger 500 and 700 series models. I have also reviewed test results from 3M regarding the minimum efficiency rating value (“MERV”) for the filters currently used in all Bair Hugger models. It is my opinion that the Bair Hugger filters are effective at removing airborne bacteria from the air that passes through them and are therefore appropriate for use in the operating room as they provide an additional removal mechanism for airborne bacteria.

A. Filtration Concepts

Bair Hugger filters are made of fibrous media – strands of borosilicate glass fibers - arranged randomly into a mesh. Fibrous filters do not work like a sieve, with uniformly sized pores in a sheet of material that exclude particles larger than the pore size. Rather, they appear more like a bird's nest when viewed under a microscope. The majority of the volume is air with only a small percentage of the volume occupied by the fibers. Chemicals called binders are often used to hold the fibers together. Typical fiber diameter can range from about 20 microns down to a few nanometers. Here is a microscopic image of a glass fiber filter media:

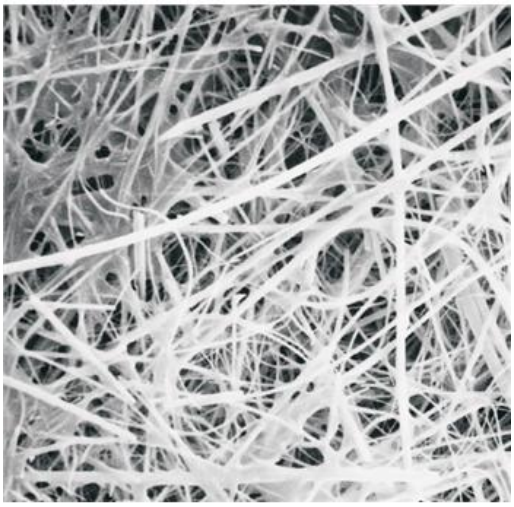

Fig. 1 Borosilicate Glass Matrix (Image from http://www.supplymylab.com/Supplies/Filter-Paper/_/PRESEP-GLASS-PREFILTERS?q=1215551&gclid=CLaC2YDBmNQCFQkIaQod3DMP7A)

Fibrous media trap particles through a combination of three mechanisms: interception, impaction, and diffusion. Interception occurs when a particle travels on a streamline close enough to a filter fiber to contact the surface of the fiber and stick to it.

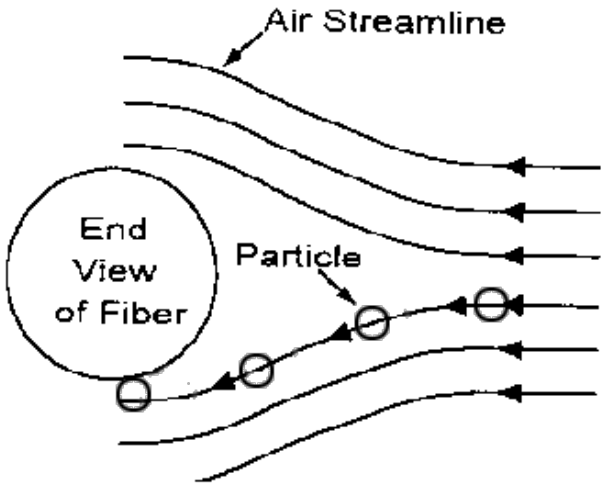

Fig. 2 Direct Interception (image from http://www.tsi.com/uploadedFiles/_Site_Root/Products/Literature/Application_Notes/ITI-041.pdf)

Impaction occurs when the momentum of a larger particle causes it to deviate from a streamline and collide with a filter fiber (rather than follow the streamline around it).

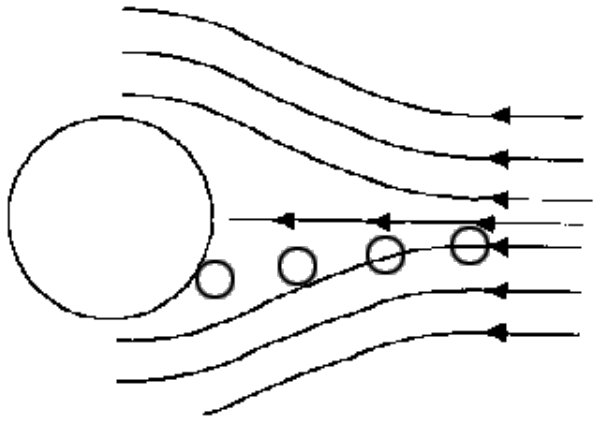

Fig. 3 Inertial impaction

Diffusion is important with very small particles (less than .1 um in size). Particles of this size constantly collide with air molecules, which causes them to travel in a random manner known as Brownian motion. This makes the particles susceptible to capture by dispersion to the fiber surface from their time averaged streamline.

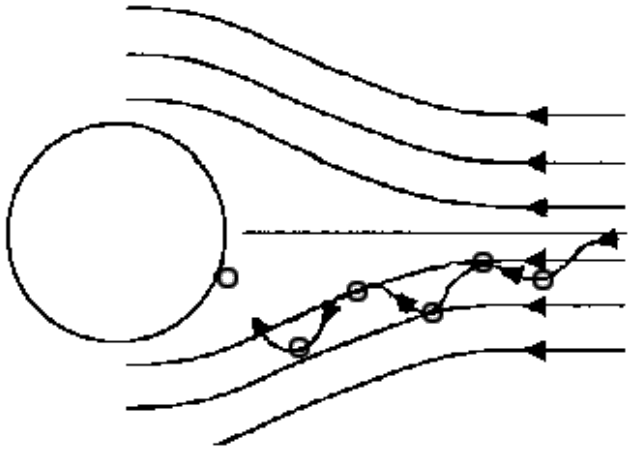

Fig. 4 Diffusion

Each of these three mechanisms plays a role in the filter's overall efficiency (its ability to capture particles of different sizes). Figure 5 shows the role that each mechanism plays at different particle sizes.

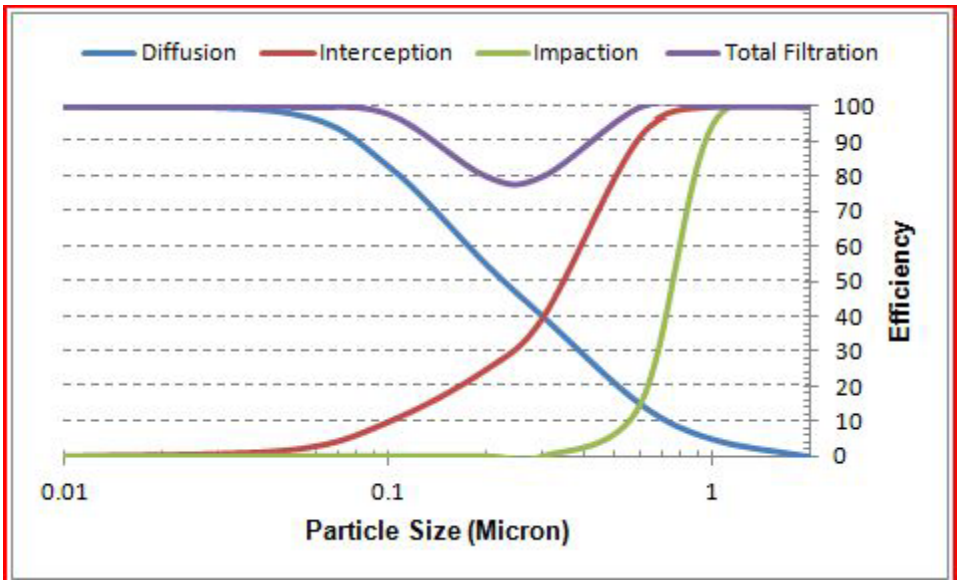

Fig. 5 Sample Filter Efficiency Curve for a Glass Fiber Filter

Figure 5 shows how the particle capture of a glass fiber media filter depends on particle size. The particle size is given in terms of aerodynamic diameter or the diameter of a particle with a density of 1 gm/cc. The results are also velocity dependent: if the mean velocity of the air that passes through the filter decreases, the minimum filter efficiency will increase. As Figure 5 shows, very small particles (less than .1 um) are captured primarily by diffusion, but diffusion drops off as particles gain size and mass. As particle sizes increase, interception and impaction play a greater role until they dominate the capture mechanism. The particles that the filter is least efficient at capturing are those that are too big to be completely captured by diffusion, but too small to be completely captured by interception or impaction. Thus, the efficiency curve for a glass filter will always dip at the "most penetrating particle size" or MPPS. The MPPS for this filter is in the range of .2-.3 microns. This aerodynamic particle size will always be the lowest point in a filter's efficiency curve (see purple curve in Fig. 5). All media filters have their most penetrating particle size in this size range as it is governed by particle physics, not the filter material or design.

The American Society of Heating, Refrigeration, and Air Conditioning Engineers ("ASHRAE") has developed a test method for determining the efficiency of filters used in HVAC systems and other related applications. The method was originally developed at Research Triangle Institute (RTI) by Jim Hanley under contract from ASHRAE. The test facility required in the Standard is similar to the one used at RTI. Potassium Chloride is used as the test aerosol as a high concentration polydisperse aerosol can be easily generated from a water solution using a nebulizer. The decision was made by the 52.2 Standards Committee to use an optical particle counter or OPC as the aerosol measuring instrument as it can provide real time aerosol concentration information versus particle size upstream and downstream of a test filter. By comparing the upstream and downstream results, the filter capture efficiency can be determined versus particle size.

An ASHRAE Standard 52.2 test facility was constructed in my laboratory at the University of Minnesota approximately 20 years ago. We included humidity control that was not specified in the standard so we could focus on filtration of bioaerosols. I served as the Principal Investigator for an ASHRAE contract to develop a Calibration Reference Device that would rely on first principles rather than calibrated optical particle counters to ensure that test facilities were in compliance with the Standard 52.2 requirements. Filters from the same lot had been sent to different test facilities with different test results so this project was an attempt to rectify this issue. Our design uses a three-stage parallel inertial impactor. The results of our project indicated that more work needed to be done to provide a reliable device at a cost that would be acceptable to the industry. At the present time, the originally specified 12 channel optical particle counters continue to be used at the filter test facilities.

Test method 52.2-2017 determines a filter's particle capture performance according to its ability to remove particles in three size ranges: 0.3-1 micron, 1-3 microns, and 3-10 microns. Test results will categorize the filter according to its Minimum Efficiency Reporting Value or "MERV". Figure 6 shows the MERV categories published in the 2017 version of the Standard:

Table 12-1 Minimum Efficiency Reporting Value (MERV) Parameters

Standard 52.2 Minimum Efficiency Reporting Value (MERV)	Composite Average Particle Size Efficiency, % in Size Range, µm			
	Range 1 0.30 to 1.0	Range 2 1.0 to 3.0	Range 3 3.0 to 10.0	Average Arrestance, %
1	N/A	N/A	$E_3 < 20$	$A_{avg} < 65$
2	N/A	N/A	$E_3 < 20$	$65 \le A_{avg}$
3	N/A	N/A	$E_3 < 20$	$70 \le A_{avg}$
4	N/A	N/A	$E_3 < 20$	$75 \le A_{avg}$
5	N/A	N/A	$20 \le E_3$	N/A
6	N/A	N/A	$35 \le E_3$	N/A
7	N/A	N/A	$50 \le E_3$	N/A
8	N/A	$20 \le E_2$	$70 \le E_3$	N/A
9	N/A	$35 \le E_2$	$75 \le E_3$	N/A
10	N/A	$50 \le E_2$	$80 \le E_3$	N/A
11	$20 \le E_1$	$65 \le E_2$	$85 \le E_3$	N/A
12	$35 \le E_1$	$80 \le E_2$	$90 \le E_3$	N/A
13	$50 \le E_1$	$85 \le E_2$	$90 \le E_3$	N/A
14	$75 \le E_1$	$90 \le E_2$	$95 \le E_3$	N/A
15	$85 \le E_1$	$90 \le E_2$	$95 \le E_3$	N/A
16	$95 \le E_1$	$95 \le E_2$	$95 \le E_3$	N/A

Fig. 6 MERV Parameters (ASHRAE 52.2-2017)

HEPA filtration, which tests filter efficiency at particles of 0.3 micron in size and smaller, is not covered by ASHRAE 52.2. For comparison with MERV numbers, HEPA filtration can be

assigned MERV numbers between 17 and 20, as shown in Fig. 7 taken from the 2007 version of ASHRAE Standard 52.2.

TABLE 2: MINIMUM EFFICIENCY REPORTING VALUE (MERV) PARAMETERS

ASHRAE Standard 52.2				ASHRAE Standard 52.1	Application Guidelines		
MERV	Particle Size Removal Efficiency, Percent in Particle Size Range, µm			Dust-Spot Efficiency Percent	Particle Size and Typical Controlled Contaminant	Typical Applications	Typical Air Filter/Cleaner Type
	0.3 to 1	1 to 3	3 to 10				
20	≥ 99.999	in 0.1 – 0.2 µm particle size		—	**< 0.3 µm** Virus (unattached) Carbon dust Sea salt All combustion smoke	Electronics manufacturing Pharmaceutical manufacturing Carcinogenic materials	HEPA/ULPA Filters*
19	≥ 99.999	in 0.3 µm particle size		—			
18	≥ 99.99			—			
17	≥ 99.97			—			
16	> 95	> 95	> 95	—	**0.3-1 µm** All bacteria Droplet nuclei (sneeze) Cooking oil Most smoke Insecticide dust Most face powder Most paint pigments	Superior commercial buildings Hospital inpatient care General surgery	**Bag Filters** – Nonsupported (flexible) microfine fiberglass or synthetic media, 12 to 36 inches deep. **Box Filters** – Rigid style cartridge, 6 to 12 inches deep.
15	85-95	> 90	> 90	> 95			
14	75-85	> 90	> 90	90-95			
13	< 75	> 90	> 90	80-90			
12	—	> 80	> 90	70-75	**1-3 µm** Legionella Humidifier dust Lead dust Milled flour Auto emission particles Nebulizer drops	Superior residential Better commercial buildings Hospital laboratories	**Pleated filters** –Extended surface with cotton or polyester media or both, 1 to 6 inches thick. **Box Filters** – Rigid style cartridge, 6 to 12 inches deep.
11	—	65-80	> 85	60-65			
10	—	50-65	> 85	50-55			
9	—	< 50	> 85	40-45			
8	—	—	> 70	30-35	**3-10 µm** Mold Spores Dust mite body parts and droppings Cat and dog dander Hair spray Fabric protector Dusting aids Pudding mix Powdered milk	Better residential Commercial buildings Industrial workplaces	**Pleated filters** –Extended surface with cotton or polyester media or both, 1 to 6 inches thick. **Cartridge filters** –Viscous cube or pocket filters **Throwaway** –Synthetic media panel filters
7	—	—	50-70	25-30			
6**	—	—	35-50	< 20			
5	—	—	20-35	< 20			
4	—	—	< 20	< 20	**> 10 µm** Pollen Dust mites Cockroach body parts and droppings Spanish moss Sanding dust Spray paint dust Textile fibers Carpet fibers	Minimum filtration Residential window air conditioners	**Throwaway** – Fiberglass or synthetic media panel, 1 inch thick. **Washable** – Aluminum mesh, foam rubber panel **Electrostatic** – Self-charging (passive) woven polycarbonate panel
3	—	—	< 20	< 20			
2	—	—	< 20	< 20			
1	—	—	< 20	< 20			

This table is adapted from ANSI/ASHRAE Standard 52.2-2007. [15]

**The last four MERV values of 17 to 20 are not part of the official standard test, but have been added by ASHRAE for comparison purposes. Ultra Low Penetration Air filters (ULPA) have a minimum efficiency of 99.999 percent in removing 0.3 µm particles, based on the IEST test method. MERVs between 17 and 19 are rated for 0.3µm particles, whereas a MERV of 20 is rated for 0.1 to 0.2 µm particles.*

*** For residential applications, the ANSI/ASHRAE Standard 62.2-2007[16] requires a filter with a designated minimum efficiency of MERV 6 or better.*

Fig. 7 MERV Parameters (with HEPA Ratings)

As Fig. 7 shows, filters with MERV parameters between 13 and 16 are considered appropriate for controlling all bacteria. The ASHRAE hospital HVAC design manual specifies MERV 14 filters for use in surgical suites. (HVAC Design Manual for Hospitals and Clinics, 2d Ed., p. 30 Table 2-4.)

B. Filtration of Bioaerosols

The filter's MPPS, which again is typically 0.2-0.3 microns, is not the relevant particle size for filtering bacteria and bacteria-carrying particles from air. Bacteria by themselves are much larger than 0.3 microns; for example, individual Staphyloccus bacteria are typically 0.8-0.9 microns in diameter. (Kowalski, W. J., W. P. Bahnfleth, T. S. Whittam (1999). "Filtration of Airborne Microorganisms: Modeling and Prediction." ASHRAE Transactions 105(2), 4-17, Table 1.) Further, Staph and other bacteria rarely travel in air as single organisms; typically they are clustered with other organisms, contained in water droplets, or attached to skin squames or dust particles. These particles are often several microns in size and are easily removed by filters in the MERV 13-16 range.

HEPA filtration is unnecessary for effective control of bacteria in air. Moreover, HEPA filtration can introduce a significant pressure drop and thereby cause more air to leak around the filter that can lead to increased passage of contaminated air compared to a MERV 14 filter. HEPA filtration will also increase the load on fan motors (because of the increased pressure drop compared with MERV 14 filters) and potentially increase maintenance costs and decrease their service life. As indicated above, the ASHRAE HVAC Design Manual for Hospitals and Clinics recommends MERV 14 filters for surgical suites, not HEPA filters.

C. The Bair Hugger Filters

Based on my review of deposition testimony and documents produced in this case, I understand that the Bair Hugger warming units incorporate a filter with media designated by the supplier, Pentair, as "M20." Arizant adopted this media for use in the Model 750 filters in the early 2000s, and in 2009 Arizant changed the media in its Model 505 filters from M10 to M20.

I have reviewed ASHRAE 52.2 test results from 3M that demonstrate that the filters incorporating the M20 filter media meet the requirements for MERV 14. I have seen no evidence that the efficiency of the M20 filter media has changed at all over the many years that 3M and Arizant have used it.

I understand that the filter media previously used by Arizant, M10, had greater efficiency in the 0.3-1 micron particle size range than the M20 media. As noted above, however, particles that carry infectious bacteria are generally larger than 1 micron. Further, the M20 media, at MERV 14, is fully capable of capturing bacteria and the particles that carry them. Thus, Arizant's switch from M10 to M20 media should not have made any difference in the Bair Hugger filters' capture of harmful pathogens.

Finally, I note that there are no ASHRAE standards for fan-blowing equipment used in operating rooms. The Bair Hugger's incorporation of a MERV 14 filter – the same minimum filtration level that ASHRAE recommends for air supplied to operating rooms – provides additional protection from airborne bacteria for patients undergoing surgery.

3. Comments on Plaintiffs' Expert Reports

Dan Koenigshofer

The majority of this report has been abstracted from the ASHRAE literature that provides design engineers guidance on the design of health care facilities. This is intended to be best practice and does not necessarily indicate how a particular facility has been designed or is operated.

On pages 20 and 21, calculations are presented that indicate that when the Model 505 Bair Hugger is operated, "at least 300 cfu/hr are blown near the patient." The initial room air concentration was estimated to be 10 cfu/ft^3 from a paper by Galson and Goddard from 1968. The purpose of this paper was to show the effect of different ventilation rates on indoor air concentration. This paper was published nearly 50 years ago and does not represent best current practice as given in the ASHRAE HVAC Design Manual for Hospitals and Clinics where room pressurization, filtration system performance and particle shedding from personnel are much better controlled. It is my professional opinion, that a room air concentration of 10 cfu/ft^3 would be considered extremely high for an OR that would use a Bair Hugger. The filter in a Bair Hugger would reduce the clean room air concentration even further before the air was sent to the blanket. Measurements of the air velocity and temperature that leave a Bair Hugger blanket were made and show that the room ventilation system is not significantly affected when the Bair Hugger is operated (Exhibit B). Thus the air is not blown near the patient. Neither are any bacteria particles that may become entrained by this air.

The following three statements have been made regarding particle motion and removal caused by the Bair Hugger:

1. The Bair Hugger operating in an OR will create turbulence at the floor, stirring settled particles.
2. The Bair Hugger draws particles off the floor into the unit. It functions much like a household vacuum cleaner.
3. The air velocity at the floor under the Bair Hugger is sufficient to entrain particles from the floor.

The Bair Hugger is provided with a feature that allows it to be attached to an IV pole. That allows the unit to be conveniently mounted approximately 18 to 24 inches above the floor so that the air velocity near the floor generated by the Bair Hugger is insignificant compared to the air velocity driven by the ventilation in the room, movement of personnel and the operation of other equipment.

Measurements of air velocity below a Model 775 Bair Hugger mounted approximately 2 ft above the floor indicated that there was no measurable difference between the air velocity near the floor when the Bair Hugger was off or turned on. Velocity measurements were also made at three

locations near the edge of the blanket where the warm air escapes into the room. None of these locations had air velocities large enough to affect the air velocity near the floor. Photos and data from these measurements are included in Exhibit B.

The manufacturer of the Bair Hugger also offers a cart to mount the unit on. When the Bair Hugger is used with this cart, the air velocity near the floor under the unit caused by the operation of a Bair Hugger is insignificant because the cart acts as a barrier between the bottom of the Bair Hugger unit and the floor.

The Bair Hugger can be placed on and operated from the OR floor. However, the maximum air velocity between the bottom of the Bair Hugger and the floor is much lower than what would be required to move or detach particles containing infectious bacteria sitting on the floor. The air velocity was measured between the bottom of a Bair Hugger and the top of a cart it was resting on to determine the velocity that would occur had the unit been sitting on a cart. The values between the bottom of the unit and a floor would be very similar. The velocity on all four sides was measured to determine the maximum value. Photos and the data recorded are provided in Exhibit B.

Using the maximum air velocity that was measured and published literature on particle motion and removal from surfaces, the results of calculations provided in Exhibit C clearly show that the physics do not support the three statements made that the Bair Hugger removes particles from the floor. The adhesion force between a hard sphere and the surface is much higher than the drag force created by the air velocity that could remove the particle. Bacteria would be more difficult to remove because they are not perfect spheres and have increased adhesion force caused by the increased contact area between the bacteria particle and the surface (Chuen-Jinn Tsai, David Y. H. Pui & Benjamin Y. H. Liu (1991) Elastic Flattening and Particle Adhesion, Aerosol Science and Technology, 15:4, 239-255). The measured maximum velocity is several orders of magnitude lower than what would be required.

The following statements have been made regarding air flow:

1. 50 -100 cfm are blown from the blanket into or near the sterile air field, causing air to move horizontally, while the intent of the HVAC system is to maintain downward air flow.
2. Air leaving the blanket at 100 to 110 F will cause upward convective air flow.
3. The hot air will lead to surgeon’s discomfort, resulting in them requesting even lower temperatures in the OR.
4. The hot air from the Bair Hugger will interfere with the downward flow of clean air from the ceiling diffuser.

Air velocity measurements made near the hip of a manikin in a simulated OR configuration did not show any measurable difference when the Model 750 Bair Hugger was turned on at high fan speed or turned off. There was no measurable effect of the Bair Hugger operation on the air velocity. Photos and the measured data are given in Exhibit B.

The temperature of the air leaving the blanket and entering the room was measured to be less than 75º F when the room temperature was about 66º F and a model 750 Bair Hugger was operated at maximum flow rate and at high fan speed as shown in Exhibit B. The claim that the air leaves the blanket between 100 and 110º F was not substantiated. The much lower temperature as measured will not have a significant effect on the movement of the warm air leaving the blanket as shown in Exhibit D.

The temperature of the air measured at the location of the hip did not show significant difference between the time when the Bair Hugger was turned off and when it was turned on with a setting of 43 ºC, as shown in Exhibit B. It is unlikely that the surgeons would notice any difference in temperature, or any change in airflow as a result of temperature change.

The following statement was made regarding the cooling load in the OR:

1. The heater in the Bair Hugger adds to the cooling load, thus requiring more air and/or colder air than the initial design.

The energy consumed by a Bair Hugger is part of the cooling load in an OR along with all the other equipment and personnel. Typical design values for sensible thermal load for equipment in an OR are 1 kW. The Model 505 Bair Hugger uses approximately 528 W, the Model 750 480 W and the Model 775 390 W on the low setting and 470 W on the high setting. All of these are well within the estimated design value of 1000 W for equipment. As the Bair Hugger uses the power to provide heat, it may be the most energy intensive piece of equipment in the OR. It is unlikely that the total cooling load for all the equipment in an OR with a Bair Hugger operating would be larger than 1000 W. There would be no reason to increase the airflow rate over the design value when a Bair Hugger is used.

The equipment thermal load is not a very important portion of the cooling load in an OR. Tempering the outdoor ventilation air is the main load as shown by Figure 8.7 of Reference 1 where lights and equipment together are shown to be 10% of the total load. A good HVAC design should be able to accommodate slight variations in the design loads.

Changing the air flow rate in an occupied OR is not desirable as this may disrupt the pressure balance between the OR and adjacent areas. It is much better to adjust the supply air temperature using the reheat coil shown in Figure 8-4 of Reference 1 to handle variations in sensible cooling load while maintaining the desired humidity level.

The following statement was made regarding the filtration level in the Bair Hugger:

1. The filters in the Bair Hugger are less efficient than those used in the HVAC system serving an OR.

The recommended MERV for final filters used to clean incoming supply air to an OR is 14 (Reference 1). A 3M report documents the results of tests on the filters used in the Bair Hugger Model 775 to be MERV 14 (Reference 2). Thus the MERV recommended for OR supply air and the measured MERV for the filters used in Bair Hugger Model 775 are equal.

The actual performance of filtration systems in hospital air handling systems can vary widely. Leaks in the seals between the filter modules and the frame, punctures in the filter media that occur sometime between filter manufacture and installation, filters that become wet, and neglected maintenance can all result in less efficient filtration system performance than designed. Therefore the performance of a specific filtration system in a hospital or clinic is site dependent and cannot always be predicted by its design. Thus the general statement given above is not valid.

References

1. HVAC Design Manual for Hospitals and Clinics, 2nd ed., 2013, Section 8.
2. 3M report RD-Test-PW-05-286536, dated 8/25/2016, by Winston Tan

Said Elghobashi

This report contains the background and results of a numerical study of airflow and particle dissemination in an operating room with and without a Bair Hugger in operation near the floor. One of the underlying assumptions, the temperature of the air that leaves the Bair Hugger blanket, is not correct. A value of 106 F (41.1 C) is used when the temperature of the air supplied to the room was 59 F (15 C). Measurements made of the air leaving a Bair Hugger blanket provided in Exhibit B showed that the warmest temperature was 75 F when the temperature setting was 43 C (109 F) and the room temperature was about 66 F. The difference between the temperature of the air entering the blanket and leaving it is caused by the thermal transport to the patient (the purpose of the Bair Hugger) and the warming of the adjacent drapes. The actual measured temperature difference between the warm air leaving the blanket and the background room air temperature was 75 – 66 or 9 F rather than the assumed value of 106 -59 or 47 F. Thus the assumed thermal buoyancy of the warm air leaving the blanket is more than a factor of 5 too large as thermal buoyancy is linearly related to temperature difference. Correcting this error in boundary condition will result in airflow that does not change nearly as much when the Bair Hugger is operated as in the results presented.

There is no indication of particle removal by the filter in the Bair Hugger although that is another particle removal or air cleaning mechanism in the OR in addition to particles attaching to surfaces and leaving with the return air.

For the particle transport, 3 million particles 10 microns in size are assumed to reside within 1 cm of the floor. It is not clear why this region near the floor was targeted, the particles should follow the air currents in the room. Three areas are considered, only one results in particles being transported to what is termed the surgical box. These are colored red in the plots.

It is unclear how many particles are assumed to start from each of the three areas near the floor but most likely the three million particles were evenly distributed among the three areas so one million begin in each. As the red colored area is the only one that shows particles reaching the surgical box, particles in this area will be the only ones considered here.

The study could have used a different number of particles starting near the floor, for example 10 million or 100 million. That should increase the number reaching the surgical box by factors of 10 and 100 respectively. This does not mean that more particles will actually reach the surgical box area. The total number of particles reaching the box is not the important result, it is the fraction of particles that begin near the floor that reach the box.

Using the assumed value of one million particles that begin near the floor in the red area, they occupy a volume of 1.35m x 0.3m x 0.01m or 0.0041 cubic meters = 0.145 ft^3. The total mass of these particles using the density of 1 gm/cubic centimeter as stated in the report (unit density)

= (number of particles x density x 3.1415 x (particle diameter)^3)/ 6

= ((10^6 x (1 gm/cm^3) x 3.1415 x (10 x10^{-6} m)^3)/6) x (10^6 μg /gm) x (10^6 cm^3/ m^3)

= 524 μg

The particle mass concentration is this total particle mass divided by the volume of air they occupy:

Mass concentration = 524 μg /0.0041 m^3 = 127,800 μg/m^3

As all the particles have a diameter of 10 μm, they are classified as a PM10 aerosol. This concentration is 852 times the current 24 hour daily maximum ambient National Ambient Air Quality Standard of 150 μg/m^3 for PM10 not to be exceeded more than once in a 3-year period. Thus this initial concentration used near the floor is several orders of magnitude higher than most unfiltered outdoor air. If a more realistic value is used, although a very conservative one, to assume that unfiltered, polluted outdoor air exists near the floor with a mass concentration of 150 μg/m^3, then the aerosol concentration results provided in this report should be adjusted accordingly.

For example, the results in Figure 31 where the red boxes are shown, the maximum number of approximately 560 should be divided by at least 852 resulting in a value less than 1.0. If very clean operating room air is assumed rather than polluted outdoor air, the resulting value becomes much lower than this. It is also very unlikely that all particles near the floor contain infectious bacteria. Therefore, it is very unlikely that any infectious particles residing near the floor in any of the three areas simulated will ever reach the critical care area.

Another method to estimate the number of culturable particles that might reach the critical care area is to assume a maximum value of 4 cfu/ft^3 in the initial red area based on concentration values given by Galson and Goddard (Reference 1) for general surgery areas. This value is from a publication nearly 50 years old so it is much larger than what one would expect today in a state-of-the-art OR so the present calculations show results much higher than what would be expected. The initial volume of the red box is 0.145 ft^3 so the total number of cfu initially in the box is:

Total cfu = 4 cfu/ft^3 x 0.145 ft^3 = 0.58 cfu

The number of these that might reach the critical area would be

Cfu-critical care = 0.58 cfu x 560/1,000,000 = 0.0003 cfu.

This is an extremely small value although as indicated above, is larger than what one would expect in a current well-maintained OR. In summary, the particle movement simulation results, if assumed to be correct, will not cause any significant contamination of the critical care area from particles located near the floor.

References:

1. Galson and Goddard, ASHRAE, 1968.

Michael Buck

This report is difficult to interpret because of a lack of clarity in the results. The plots presented have an undefined logarithmic scale on the vertical axis (that may be particle number counts) and appear to have a time scale on the horizontal axis. Several different conditions were tested but there is no indication of when each condition started and ended. Transients are evident between one condition and another when the results change with time. It is not known whether each test was performed for a sufficiently long period of time so that the transients do not influence the results. Buck did not replicate his tests. A minimum of three replicates at each condition is the norm for statistical accuracy. There are no blank test results showing particle counts with zero measurable particles entering the particle counter through one or more HEPA filters at the inlet so the background counts are unknown. The probe seems to be aligned with the air exiting the hose but that is not sufficient for isokinetic sampling. The mean velocity within the probe must be equal to the velocity in the surrounding air. There is no indication that this was considered. Using the same probe, the velocity within is fixed by the sampling pump in the instrument. However, the surrounding air velocity can vary depending on where the sample is taken. Without true isokinetic sampling, the particle concentration results can be biased.

It appears that total numbers of particles were measured. It is well known that the number concentration of particles increases dramatically as the particle size is reduced. This is shown on some of the figures. These particles are too small to contain bacteria.

No measurement of the nature of the particles was provided. Culture plates could have been used with an Andersen impactor or pour plates with an all glass impinger (AGI) to determine if any of the particles measured were culturable. Non-culturable particles collected on filters could have been analyzed for their chemistry to determine whether they originated from within the machine or simply passed through.

It is unclear from the figures when the filter was installed and when it had been removed so no definitive conclusion can be drawn regarding filter performance based on this report.

Yadin David, William Jarvis, Michael Stonnington

Each of these reports comments on Tsai et al., who provided some information on an event at MD Anderson Cancer center where a malfunction within an operating Bair Hugger caused black spots to be deposited on the skin of a patient and surroundings blankets. The black spots were assumed to be soot generated from an electrical malfunction within the unit and appeared to be

deposited near the location of holes in the blanket. I agree with Tsai's assessment that the particles were soot. However I disagree with the suggestion that the passage of soot particles through the Bair Hugger blanket provides evidence that pathogens can pass through the Bair Hugger system.

Soot particles are formed from a chemical reaction as illustrated in Figure 8. The particle formation begins as the molecular clusters grow into very small spherical particles about 20 nm in size. These in turn then aggregate to form chains that can be anywhere from about 30 to 40 nm in length to about 500 nm. A photo of two of these typical aggregate particles is shown in Figure 9 where the length scale bar in the lower left hand corner is 50 nm. The smaller of the two particles is about 70 nm in size whereas the larger one has a length of about 500 nm. The smaller particle has an aerodynamic diameter similar to its physical size because it is quite compact and roughly spherical in shape. The larger chain has an aerodynamic diameter much less than its length because it is much less dense and may be approximately 120 nm. The aerodynamic diameter of a particle determines its settling rate and how it behaves as it passes through a filter.

The soot particles that were observed to have deposited on the patient and surrounding blankets most likely were in the size range discussed above. Their aerodynamic diameter is much less than single bacteria spores and clumps of bacteria or bacteria attached to other material. Therefore the deposited soot is not a good indication that much larger bacteria particles would follow the same path and deposit similarly.

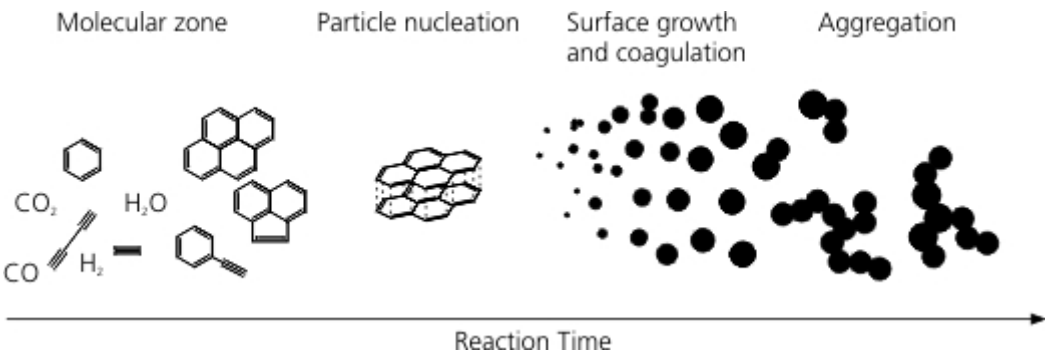

Fig. 8. Soot formation process.

http://www.forbrf.lth.se/english/research/measurement-methods/laser-induced-incandescence-lii/

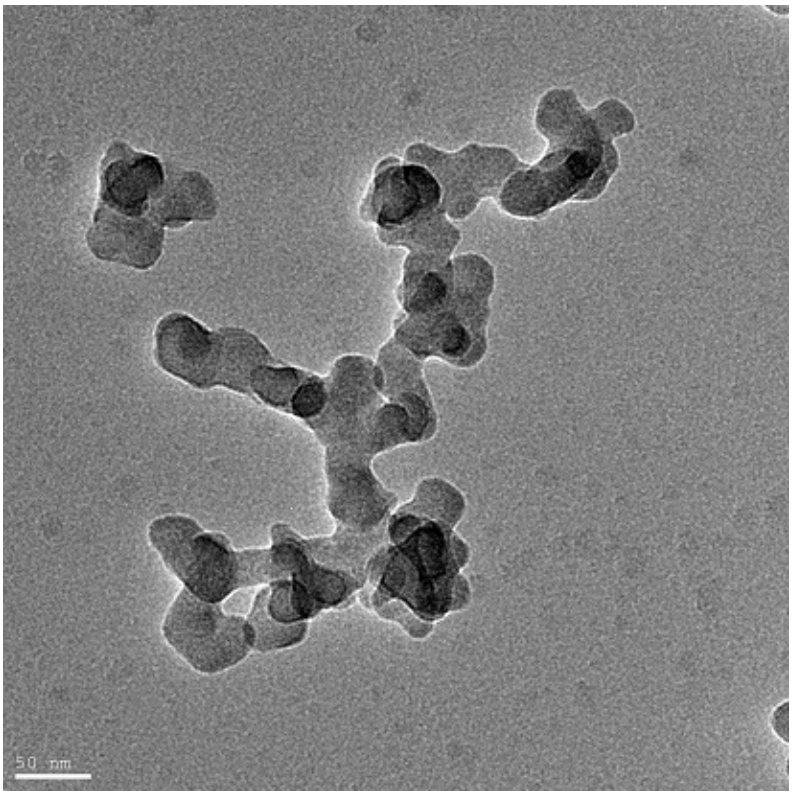

Fig. 9. Photo of agglomerated soot particles.

http://www.ltt.uni-erlangen.de/en/research/particle-measurement/

The materials I considered in my analysis are attached as Exhibit E. I reserve the right to supplement my analysis and provide additional opinions and observations in response to newly received information.

June 1, 2017

Thomas H. Kuehn, Ph.D.